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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/397,558	09/16/99	LAL P	PF-0527-1DIV

HM12/0222

LEGAL DEPARTMENT
INCYTE PHARMACEUTICALS INC
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EXAMINER	
HARRIS,A	

ART UNIT	PAPER NUMBER
1642	8

DATE MAILED: 02/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/397,558	Lal et al.
Examiner	**Group Art Unit**
Alana M. Harris, Ph. D.	1642

☒ Responsive to communication(s) filed on *Dec 30, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1, 2, 14-18, and 21-27* is/are pending in the applicat

Of the above, claim(s) *14-18 and 23-26* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 2, 21, 22, and 27* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2, filed 9/16/99.

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 1, 2 , 21-22 and 27) in Paper No.6 (filed January 8, 2000) is acknowledged. The traversal is on the grounds that the Groups are interrelated as to be capable of search of all claims would not pose an undue burden. This is not found persuasive.

The argument that Groups I and III are not independent and distinct inventions is not found persuasive for the reasons set forth in the restriction requirement (Paper No. 4, mailed October 26, 1999). As to the question of burden of search, the claims of Groups I-VI are classified differently, necessitating different searches in the U.S. Patent shoes. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Clearly different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is adhered to.

The requirement is therefore made FINAL. Further, Group VI involves a method step, which require additional searching.

However, the policies set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86 will be followed. Method claims limited to the scope of the allowable product claims will be rejoined and examined at the time the product claims are indicated as being allowable.

2. Claims 21-27 have been added.

Claims 3-13, 19 and 20 have been canceled.

Claims 1, 2 and 14-16 have been amended.

Claims 1, 2, 14-18 and 21-27 are pending.

Claims 14-18, 20 and 23-26, drawn to non-elected inventions are withdrawn from examination.

Claims 1, 2, 21, 22 and 27 are examined on the merits.

Information Disclosure Statement

3. Applicant notified the Office in the Information Disclosure Citation (Paper No. 2, filed September 16, 1999) that listed documents to be considered were originally filed in parent case #09/083,521. Parent case #09/083,521 was unavailable to the Examiner, thus all documents "lined through" were not reviewed during examination. Applicant is invited to resubmit documents for consideration.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, 21, 22 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

a. Claims 1c, 1d and 2 are broadly drawn to "a naturally-occurring amino acid sequence having at least 90% sequence identity to the sequence of SEQ. ID. NO:1 and SEQ. ID. NO: 2" coupled with biological activity or "at least one functional characteristic". The specification while being enabling for the polypeptide having the amino acid sequences of SEQ. ID. NO:1 and SEQ. ID. NO:2, does not reasonably provide enablement for variants that have at least 90% sequence identity. There is no guidance as to how to make these divergent sequences, which possess function with the absence of any information on what functions the native protein possesses. Likewise, it would seem that specific function(s) would be required to make a protein useful for the applications disclosed in the specification. The specification doesn't teach what those are or how to determine what they are. This could possibly be a vast collection of polypeptides and the specification provides inadequate instruction to allow one skilled in the art to make and use the said naturally-occurring polypeptides having at least 90% sequence identity with a reasonable expectation of success and without undue experimentation.

b. Claims 22 and 27 are broadly drawn to "a pharmaceutical composition comprising a polypeptide". The specification while being enabling for a composition comprising a

polypeptide of claims 1 and 21 and a pharmaceutically acceptable carrier, does not reasonably provide enablement for a "pharmaceutical composition" comprising these same components. Claims drawn to "pharmaceutical compositions" are broadly interpreted to read on compositions effective for use as *in vivo* human therapeutics. The polypeptide of the invention is completely uncharacterized functionally. The mere fact that it seems to be expressed in prostate tissue is not sufficient to establish that it plays a role in the pathology or etiology of diseases in these tissues. In the absence of an established role of the polypeptide in diseases of prostate tissue it is impossible to predict what if any therapeutic effect the administration of the polypeptide would have for the treatment of prostate disorders and cancer. The selection and development of such human therapeutics is art known to be highly unpredictable. The specification exemplifies no examples of the effective use of the effective use of the polypeptide as a pharmacological agent and no such uses are art known. The specification lists a number of organ systems in which these "prostate growth-associated proteins" could be expressed, i.e. breast, brain and the adrenal gland for example. This reasonably conjures the question as to how selective the expression of the claimed proteins clearly is. Could these claimed proteins reasonably be selective and specific in their application of detecting a marker for **just** prostate assays/diagnoses when their expression can not be limited to just prostate? Accordingly, those skilled in the art cannot rely on this information to identify the expression of these polypeptides solely as specific markers in the prostate. One skilled in the art would not know how to use the claimed compositions as the component polypeptide was not known prior to the applicant's invention. Its function is not

known and is not disclosed in the specification, which speculates merely that it is "associated" with the prostate. The specific association is not elucidated. None of the "associated" proteins claimed are known to be useful for the treatment of prostate disorders and/or cancer. Therefore, due to the unpredictability of therapeutics and the absence of any evidence concerning the effectiveness of the claimed pharmaceutical composition as a pharmacological agent, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use with a reasonable expectation of success, the invention commensurate in scope with this claim. The association provides no guidance as to how the instant polypeptides can be employed as therapeutic nor a basis to predict their efficacy. The applicant is advised to amend the claim to delete the recitation of "pharmaceutical".

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 2, 21, 22 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The recitations "naturally-occurring", 'biologically-active" and "antigenically-active" in claim 1 are not clear. What functional properties are bestowed upon these designated sequences described by these terms?

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by either Accession #Q20236 (November 1996). Accession #Q20236 discloses a substantially purified polypeptide comprising an amino acid sequence that is a fragment of the amino acid sequence of SEQ. ID. NO:1, which would be antigenic and is the same as that claimed.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by either Yu et al. (Genome Res. 7(4):353-8, 1997) or Andersson et al. (Anal. Biochem. 236(1):107-113), as evidenced by Accession #O75539. Yu et al. and Andersson et al., as evidenced by Accession #O75539 disclose a substantially purified polypeptide comprising an amino acid sequence that is a fragment of the amino acid sequence of SEQ. ID. NO:2, which would be antigenic and is same as that claimed.

11. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent #5,723,315. Sequence 9 in U.S. Patent #5,723,315 discloses a substantially purified polypeptide comprising an amino acid sequence that is a fragment of the amino acid sequence of SEQ. ID. NO:2 and would be antigenic and is the same as that claimed.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Accession #Q20236, Yu et al., Andersson et al. and U.S. Patent #5,723,315 in view of Harlow and Lane (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, 1988). As previously discussed, the aforementioned references teach a substantially purified polypeptide comprising a fragment of amino acid sequences, SEQ. ID. NO. 1 and SEQ. ID. NO. 2 of claim 1. Accession #Q20236, Yu et al., Andersson et al. and U.S. Patent #5,723,315 do not teach polypeptides comprised in a composition such as an adjuvant contained with saline, mineral oil or aluminum hydroxide.

Harlow and Lane teach the pharmaceutically acceptable diluent of pH neutral, phosphate buffered saline solution for the storage of polypeptides and the production of adjuvants. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to formulate a pharmaceutical composition comprising a carrier/excipient and the polypeptides of claim 1 in order to store the polypeptides in solution for the purpose of making an adjuvant. One of ordinary skill in the art would have been motivated to store the polypeptides in saline because Harlow and Lane teach that these components are necessary when producing an effective adjuvant. Moreover, one of ordinary skill in the art would have had a reasonable expectation of success in placing the polypeptides of claim 1 in a pharmaceutically acceptable carrier such as saline because this protocol is a standardly used immunological technique described in basic antibodies manual such as Harlow and Lane.

Because pharmaceutically acceptable carriers such as sterile saline solution and phosphate-buffered-saline solution were well known in the art, one of ordinary skill would have known how to formulate a pharmaceutical composition comprising a carrier/excipient and the instantly claimed polypeptides.

When the claim is directed to a product, the preamble or intended use is generally nonlimiting if the body of the claim is directed to an old composition and the preamble merely recites a property inherent in the old composition. [*Kropa v. Robie*, 88 USPQ 478, 480 - 81 (CCPA 1951); see also MPEP 2111.02]. Thus, art which reads on a compound may also be

applied to pharmaceutical compositions consisting essentially of said compound and a suitable pharmaceutical carrier.

It has been held by the Court that a compound and a carrier are obvious, if it is obvious in the art to utilize a carrier with related compounds. See In re Rosicky, 125 USPQ 341 (CCPA 1960).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703) 306-5880. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
Patent Examiner, Group 1642
February 17, 2000

NANCY A. JOHNSON, PH.D
PRIMARY EXAMINER